

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/339,103	06/24/99	KILGER	C P1614-8090

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HM22/1003

EXAMINER

HORLICK, K

ART UNIT	PAPER NUMBER
1656	9

DATE MAILED: 10/03/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. 09/339,103	Applicant(s) Kilger et al.
Examiner Kenneth R. Horlick	Group Art Unit 1656



Responsive to communication(s) filed on \_\_\_\_\_

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 1-126 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-126 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) 08/991,184

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 6 (2 pages)

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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1. Claims 5-7, 9-12, 41-45, 68-70, 72-75, and 104-108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are confusing because of the language "or a functional derivative thereof", as it cannot be determined what is encompassed by this language.
2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-126 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-58 of copending Application No. 09/357,166 in view of Gelfand et al. (US 5,310,652) and Birch et al. (5,677,152).

This is a provisional obviousness-type double patenting rejection.

The copending claims are drawn to methods and kits for simultaneously amplifying and sequencing nucleic acids, requiring two different polymerases, wherein one has a higher affinity towards a chain-terminating nucleotide relative to the other.

The copending claims do not encompass direct application of the methods/kits to RNA wherein at least one of the polymerases has reverse transcriptase activity, nor modification of said methods/kits to include a polymerase-inhibiting agent.

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Gelfand et al. disclose a one-tube, one-polymerase amplification of target RNA sequences using a polymerase with reverse transcriptase activity (see, for example, the abstract).

Birch et al. disclose the advantageous use of a polymerase-inhibiting agent, including antibodies and various anhydrides, in nucleic acid amplifications (see, for example, the abstract and Fig. 1).

One of ordinary skill in the art would have been motivated to modify the methods of the copending claims by application towards RNA using a polymerase with reverse transcriptase activity, and/or application of a polymerase-inhibiting agent, because Gelfand et al. disclosed the advantages of combined reverse-transcription and amplification, and Birch et al. disclosed the benefits of using such an agent in amplification reactions. In other words, these would have been logical, straightforward applications to achieve expected improvements. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make the claimed kits and carry out the claimed methods.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koster et al. (US 5,928,906) in view of Gelfand et al. (US 5,310,652) and Birch et al. (5,677,152).

These claims are drawn to methods and kits for simultaneously amplifying and sequencing nucleic acids, requiring two different polymerases, wherein one has a higher affinity towards a chain-terminating nucleotide relative to the other, further comprising: direct application to RNA wherein at least one of the polymerases has reverse transcriptase activity; and/or use of a polymerase-inhibiting agent.

Koster et al. disclose methods and kits for simultaneously amplifying and sequencing nucleic acids, requiring two different polymerases, wherein one has a higher affinity towards a chain-terminating nucleotide relative to the other (see especially column 3, lines 25-57, column 7, lines 43-67 and column 8, lines 1-6, and Example 1 in columns 11-12).

This patent does not disclose DNA polymerase-mediated reverse transcription coupled to PCR amplification, nor the use of polymerase-inhibiting agents.

Gelfand et al. disclose a one-tube, one-polymerase amplification of target RNA sequences using a DNA polymerase with reverse transcriptase activity (see, for example, the abstract).

Birch et al. disclose the advantageous use of a polymerase-inhibiting agent, including antibodies and various anhydrides, in nucleic acid amplifications (see, for example, the abstract and Fig. 1).

One of ordinary skill in the art would have been motivated to modify the method of Koster et al. by application towards RNA using a polymerase with reverse transcriptase activity, and/or application of a polymerase-inhibiting agent, because Gelfand et al. disclosed the advantages of combined reverse-transcription and amplification, and Birch et al. disclosed the benefits of using such an agent in amplification reactions. In other words, these would have been logical, straightforward applications to achieve expected improvements. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make the claimed kits and carry out the claimed methods.

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4. No claims are free of the prior art.
5. Birch et al. (US 5,773,258) is made of record as a reference of interest.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kenneth Horlick whose telephone number is (703) 308-3905. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers for Group 1600 are (703) 308-4556 and 308-4242.

KENNETH R. HORLICK  
PRIMARY EXAMINER  
GROUP 1600

9/28/00

*Kenneth R. Horlick, Ph.D.*